

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



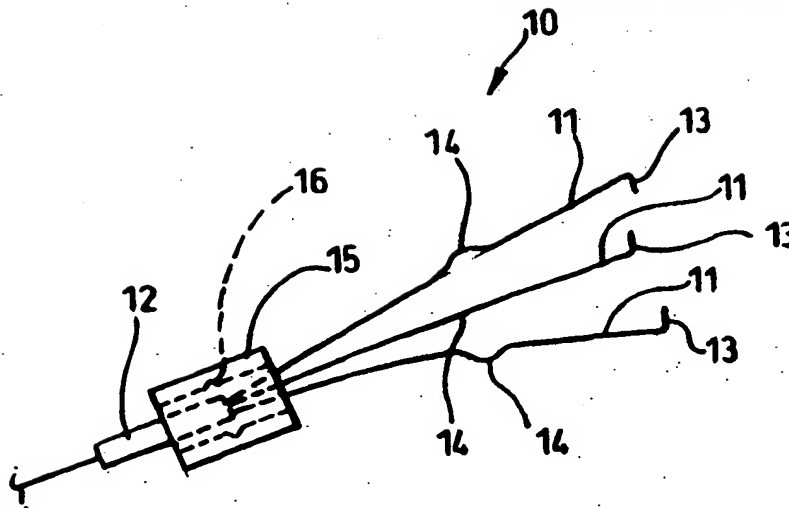
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶: A61B 17/122	A1	(11) International Publication Number: WO 99/20183 (43) International Publication Date: 29 April 1999 (29.04.99)
(21) International Application Number: PCT/GB98/03147 (22) International Filing Date: 21 October 1998 (21.10.98) (30) Priority Data: 9722203.8 21 October 1997 (21.10.97) GB (71) Applicant (for all designated States except US): UNIVERSITY COLLEGE LONDON [GB/GB]; Gower Street, London WC1E 6BT (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): MILLS, Timothy, Noel [GB/GB]; Flat 4, 45 Newman Street, London WC1N 3PA (GB). SWAIN, Paul [GB/GB]; 41 Willow Road, London NW3 1TN (GB). GONG, Feng [CN/GB]; Shropshire House, 11-20 Capper Street, London WC1E 6JA (GB). (74) Agent: ELKINGTON AND FIFE; Prospect House, 8 Pembroke Road, Sevenoaks, Kent TN13 1XR (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: SURGICAL CLIP

(57) Abstract

A surgical clip is provided for clipping tissue, for example for clamping a bleeding blood vessel. The clip has at least three arms which are secured together at their proximal ends and have distal end portions which, in the rest state thereof, form a diverging, non-coplanar array. The clip has a sleeve which is movable from a position in which the arms adopt their rest state to a position in which the distal end portions of the arms are closer together to engage tissue.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

SURGICAL CLIP

This invention relates to a surgical clip for use in endoscope clipping procedures.

Clips of this type are known, and are employed, for example, in haemostasis (stopping bleeding) and marking medically significant sites (e.g. the sites of tumours) in the gastrointestinal tract. Such clips have been used for a considerable number of years with rigid endoscopes. However, they have significant shortcomings, and with the increased use of endoscopy in recent years, for example as the results of the development of flexible endoscopy, there is, and has been for some time, a need for improved clips.

A widely used prior art clip is shown in Figure 1 of the accompanying drawings, in the configuration it has prior to use. As can be seen, this comprises a pair of arms 1 of resilient material which cross one another to form a general X-shape, the proximal ends of the arms received being in a sleeve 2 which is longitudinally slidable thereon. The proximal ends of the arms are connected, at a point which, in the view of Figure 1, is within the sleeve 2, to one end of a connector 3. The other end of the connector 3 can be connected by means of the opening 4 to a clip fixing device.

The arms have proximal portions 1a which, at their maximum distance from one another, are slightly further apart than the internal diameter of the mounting 2, and distal portions 1b which extend to a point where they are

much further apart. The distal portions terminate in engaging portions 1c adapted to engage body tissue.

In use, the sleeve 2 is slid rightwardly, by an actuating device. The initial effect of this is to compress the proximal arm portions 1a and thereby cause the distal arm portions 1b to move even further apart. The arms are then positioned so that the engaging portions 1c are located in the correct position in relation to the tissue which is to be clipped. The sleeve 2 is then slid further rightwardly, so that it engages the distal arm portions 1b and forces them towards one another, thus causing the tissue to be engaged by the engaging portions 1c.

One major drawback with the clip just described is that in many situations it can only effect clipping if it is oriented in one particular way. To allow for this, the clip is applied using an actuator which allows the clip to be rotated about its longitudinal axis. However, not only does this complicate the clipping procedure, but it cannot always be employed effectively. For example, when trying to clip an artery in a bleeding ulcer the surgeon may not be able to tell which way the artery runs, and hence will not know which way to orientate the clip.

An object of the present invention is to avoid this problem. Particular embodiments of the invention will now be described below which have additional advantages.

According to the present invention there is provided a surgical clip comprising at least three arms which are secured together at their proximal ends and have distal end

portions which, in the rest state thereof, form a diverging, non-coplanar array, and a sleeve movable from a first position in which the arms adopt their rest state to a second position in which the distal end portions of the arms are closer together to engage tissue which is to be clipped.

The invention is further described below with reference to Figures 2a to 6c of the accompanying diagrammatic drawings, in which:

Figure 2a and 2b are perspective and end views respectively of an embodiment of the invention;

Figures 3, 4 and 5 show successive stages in the use of the embodiment of Figure 2; and

Figures 6a to 6c show three types of surface pattern which may be provided at the tips of the arms used in the clip of the invention.

As shown in Figures 2a and 2b, a clip 10 according to the invention comprises three resilient arms 11 which are attached at their proximal ends to a common mounting 12 and which, in the illustrated rest position, diverge towards the proximal ends. As can be seen from Figure 2b, the diverging arm portions are non-coplanar and, as considered in an end projection, diverge approximately equiangularly, i.e. at about 120° to one another. It is to be understood, however, that equiangular divergence is not essential. It is further to be understood that there could be more than three arms, for example four arms.

Each arm 11 has a tip portion 13 extending at an

angle, for example at about 90°, to the adjoining portion of the arm. For example, each arm can be a resilient metal wire, and each tip portion 13 can be an integral end portion of the respective wire. If desired, the tip portion 13, or the whole of each arm, can be coated with a plastics material, for example by injection moulding, to reduce the risk of damage to the patient's tissue. Preferably, the tip portions are so oriented that when the diverging arm portions are brought together (see below) the tip portions extend at least approximately parallel to one another, so that any two adjacent tip portions can form a parallel sided, tissue engaging clamp. Alternatively or additionally, the arms can be made of slightly different lengths to one another, so that when they are brought together the tip portions of the arms do not prevent the arms coming close enough together to engage the tissue securely. Other possibilities for the tip portions are described below. Part way along its length, each diverging arm portion has a V-shaped section 14. The purpose of these sections is explained below. A sleeve 15 is slidably received on the arms. The bore of the sleeve has a widened section 16 intermediate its length.

The operation of the clip 10 can best be understood by consideration of Figures 3 to 5, which show the use of the clip in clamping a bleeding blood vessel 20. The clip is introduced into the patient's body by means of an endoscope 21, for example a flexible endoscope, having a biopsy channel 22. The clip 10 is held in place with respect to

the endoscope by a wire 23 running in a sheath 24, both of which extend along the biopsy channel 22. The clip 10 is releasably attached to the wire 23. In Figures 3 and 4 this is shown, by way of example, as being by the clip being provided with a hook 25 and the wire 23 being a double run of wire which extends from the proximal end of the endoscope down the biopsy channel, round the hook and back to the proximal end, the proximal ends of the wire being held by a wire clamp 26.

The endoscope, with the clip mounted on the distal end thereof, as shown, is introduced into the patient's body until the clip is adjacent the location where the blood vessel is located. To clamp the blood vessel the clip is then moved towards the blood vessel until two of the arms pass one side of the vessel and the third arm passes the other side. It will be appreciated that it is not necessary to rotate the clip about its longitudinal axis to achieve this. It will be achieved whatever the rotational orientation of the clip.

The endoscope is then moved further longitudinally, i.e. towards the site where the clip is to be attached to the blood vessel, whilst a restraining rightward force is exerted on the wire clamp 26. Since the external size of the sleeve 15 is greater than the internal size of the biopsy channel, the sleeve is thereby forced leftwardly with respect to the arms 11 until the V-shaped sections 14 of the arm engage in the widened section 16 of the sleeve bore. The situation is then as shown in Figure 4.

Finally, the wire clamp 26 is released and the endoscope 21 withdrawn, leaving the clip 10 in place on the blood vessel, as shown in Figure 5.

Various modifications may be made to the clip described above. For example, instead of merely using portions of the wire arms as the tip portions 12, additional members could be attached to the ends of the arms, and such additional members could carry, on those faces between which the tissue to be clipped, serrations or other patterns to improve the grip of the members on the tissue. Examples of some possible patterns are shown in Figures 6a to 6c.

Furthermore, modifications may be made to the device by which the clip is installed. For example, the function of the components 21 to 24 as regards clip installation may be taken over by a wire-wound cable (i.e. a Bowden-type cable) which is located in the biopsy channel of an endoscope. This gives greater freedom as regards use of the device, though it also means that the elements of the installation device must be further reduced in size, compared to the "front-loading" method described with reference to Figures 3 to 5m which allows larger, and therefore stronger, clips to be used.

CLAIMS:

1. A surgical clip comprising at least three arms which are secured together at their proximal ends and have distal end portions which, in the rest state thereof, form a diverging, non-coplanar array, and a sleeve movable from a first position in which the arms adopt their rest state to a second position in which the distal end portions of the arms are closer together to engage tissue which is to be clipped.

2. A surgical clip according to claim 1, wherein there are precisely three arms.

3. A surgical clip according to claim 2, wherein the arms diverge approximately equiangularly from one another, as considered in an end projection.

4. A surgical clip according to any preceding claim, wherein each arm is in the form of a resilient metal wire.

5. A surgical clip according to any preceding claim, wherein each arm has a main portion and a tip portion extending at an angle to the main portion.

6. A surgical clip according to claim 5, wherein the tip portions are so orientated that when the arms are brought together the tip portions extend at least approximately

parallel to one another.

7. A surgical clip according to claim 5 or 6, wherein the tip portion and main portion of each arm are integral with one another.

8. A surgical clip according to claim 5, 6 or 7, wherein the arms are of different length to one another.

9. A surgical clip according to claim 5 or 6, wherein the tip portions are provided by additional members attached to the ends of the arms.

10. A surgical clip according to claim 9, wherein the said additional members have tissue gripping faces provided with a pattern adapted to increasing the grip thereof on the tissue to be clipped.

11. A surgical clip according to any preceding claim, wherein each arm has an outwardly extending portion adapted to be engaged by the sleeve when it moves from its first to its second position.

12. A surgical clip according to claim 11, wherein each said outwardly extending portion is a V-shaped portion.

13. A surgical clip according to claim 11 or 12, wherein the sleeve has a bore with a widened section intermediate

its length, the widened portion being adapted to receive the outwardly extending portions of the clip.

14. A surgical clip according to any preceding claim, further comprising means for releasable attachment to means for exerting on the clip a force to cause the sleeve to move from its first position to its second position.

15. A combination of a surgical clip according to claim 14 and an endoscope on the distal end of which the clip is mounted.

16. A combination according to claim 15, wherein the force exerting means passes through a channel in the endoscope to the proximal end of the endoscope, and wherein the sleeve has a cross-section too large to permit it to pass through the said channel.

17. A method of engaging tissue to effect clipping thereof, comprising:

providing a surgical clip comprising at least three arms which are secured together at their proximal ends and have distal end portion which, in the rest state thereof, form a diverging, non-coplanar array, and a sleeve movable from a first position in which the arms adopt their rest state to a second position in which the distal end portions of the arms are closer together to engage tissue which is to be clipped; and

moving the sleeve from its first position to its second position.

18. A method according to claim 17, wherein the clip is initially mounted at the distal end of an endoscope, the endoscope, with the clip mounted thereon, is moved to the location of the said tissue, and the sleeve is then moved from its first position to its second position.

1/2

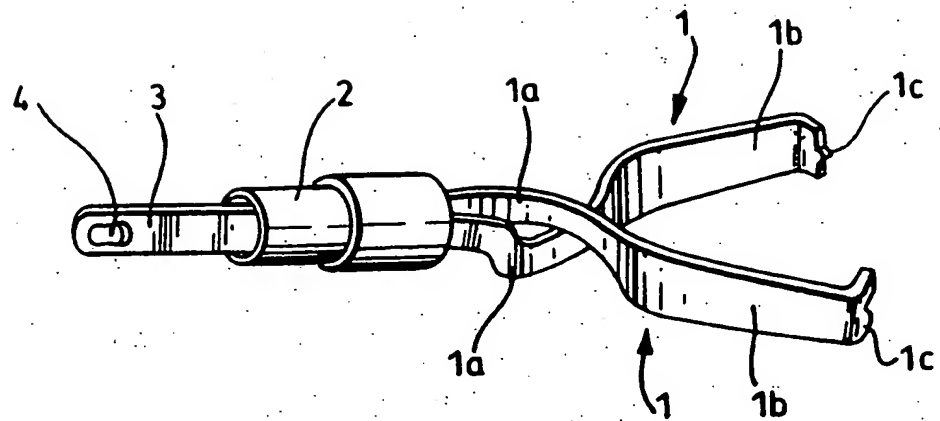


Fig.1.

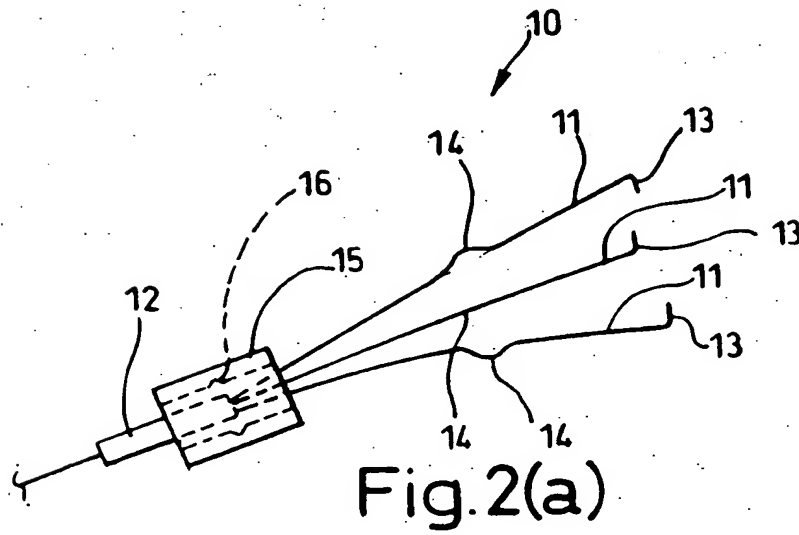


Fig.2(a)

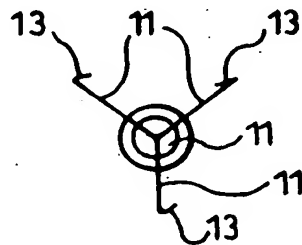


Fig.2(b)

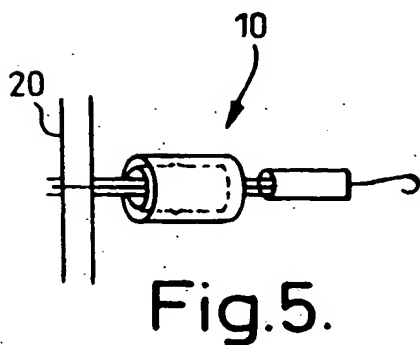
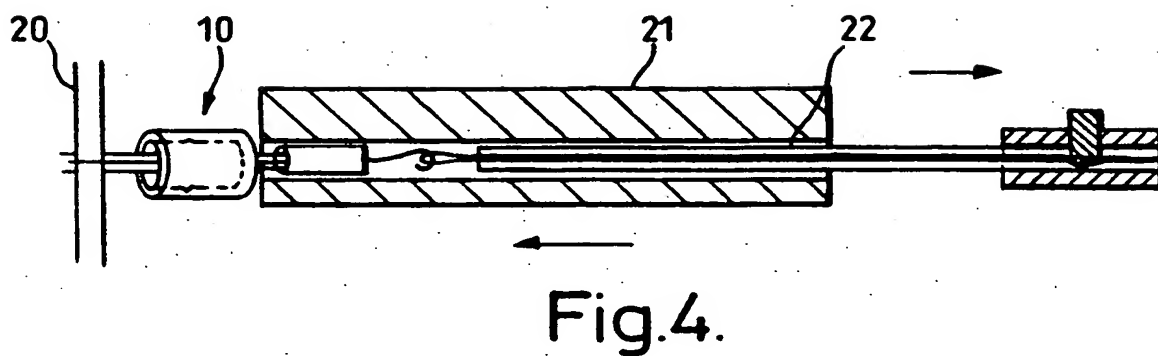
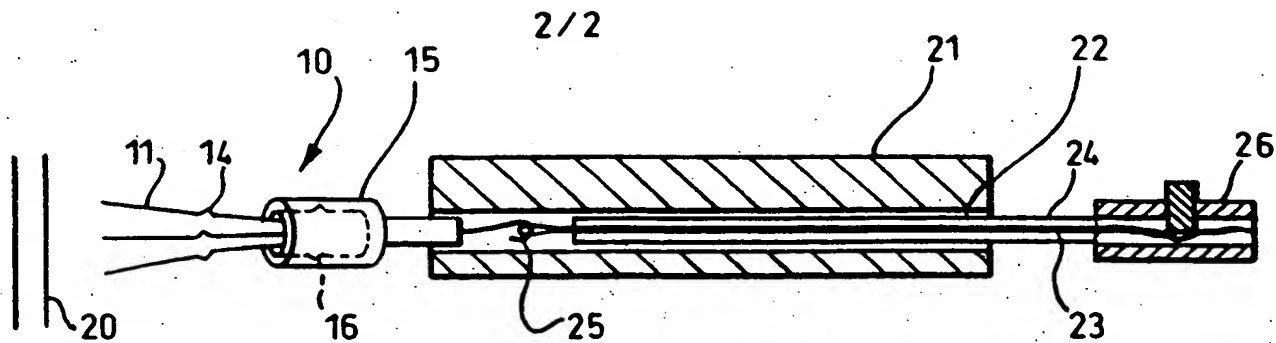


Fig. 6(a)



Fig. 6(b)



Fig. 6(c)

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 98/03147

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 91 08708 A (YOON) 27 June 1991	1, 11, 13-15
Y	see page 42, line 32 - page 43, line 17; figure 37	2-5, 7, 8
Y	US 4 174 715 A (HASSON) 20 November 1979 see figures 1, 6, 11	2-5, 7, 8
A	US 5 634 932 A (SCHMIDT) 3 June 1997 see column 5, line 47 - line 61; figures 8-12	4, 11, 12
A	DE 197 07 382 A (OLYMPUS) 4 September 1997 see column 3, line 3; figures 1, 4-6	4-7, 11, 12, 14-16
A	EP 0 567 965 A (3M) 3 November 1993 -/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

19 January 1999

Date of mailing of the international search report

26/01/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Barton, S

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 98/03147

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 520 701 A (LERCH) 28 May 1996 -----	

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 98/03147

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 98/03147

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9108708 A	27-06-1991	US 5100418 A AT 164053 T DE 69032165 D DE 69032165 T EP 0504312 A EP 0701796 A EP 0701797 A ES 2112858 T US 5437680 A WO 9707741 A US 5542949 A US 5480405 A US 5478353 A US 5366459 A US 5445167 A	31-03-1992 15-04-1998 23-04-1998 06-08-1998 23-09-1992 20-03-1996 20-03-1996 16-04-1998 01-08-1995 06-03-1997 06-08-1996 02-01-1996 26-12-1995 22-11-1994 29-08-1995
US 4174715 A	20-11-1979	NONE	
US 5634932 A	03-06-1997	AU 7328296 A CA 2232995 A DE 19681595 T GB 2320199 A WO 9713466 A	30-04-1997 17-04-1997 15-10-1998 17-06-1998 17-04-1997
DE 19707382 A	04-09-1997	JP 9289989 A US 5766189 A	11-11-1997 16-06-1998
EP 567965 A	03-11-1993	CA 2094463 A US 5441509 A	29-10-1993 15-08-1995
US 5520701 A	28-05-1996	DE 4319829 C AT 168875 T CA 2124719 A DE 59406536 D EP 0630615 A JP 2575292 B JP 7008499 A	25-08-1994 15-08-1998 17-12-1994 03-09-1998 28-12-1994 22-01-1997 13-01-1995